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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,279	07/18/2001	Kazumi Iijima	114474-13-FESI00001	5027
38492	7590	05/30/2006	EXAMINER	
WILLKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099			AUGHENBAUGH, WALTER	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/647,279

Applicant(s)

IIJIMA, KAZUMI

Examiner

Walter B. Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgement of Applicant's Amendments***

1. The amendments made in claims 1 and 6 in the Amendment filed March 17, 2006 (Amdt. E) have been received and considered by Examiner.
2. New claims 11-20 presented in Amdt. E have been received and considered by Examiner.
3. The cancellation of claim 10 in Amdt. E has been acknowledged by Examiner.

### ***Election/Restrictions***

4. Upon consideration of claim 6 as amended, Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 1, drawn to a plastic syringe barrel.

Group II, claim 6, drawn to a method for improving a plastic syringe barrel.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I has a special technical feature directed to a helically continuous screw thread that is not required for Group II.

5. Newly submitted claims 15-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

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claims 18-20 depend upon claim 6 and therefore belong in Group II, and Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 for the reasons provided above in this Office Action, and

claims 15-17 constitute Group III, where the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I has a special technical feature directed to a luer lock portion formed in the nozzle portion of a plastic syringe barrel that is not required for Groups II or III, Group II has a special technical feature directed to forming all of an inner surface of the luer lock portion into a surface subjected to surface roughening treatment that is not required for Groups I or III, and Group III has a special technical feature directed to forming an outer cylinder (which need not be the outer cylinder of claim 1) and an inner cylinder (which need not be the inner cylinder of claim 1) in a nozzle portion of the syringe barrel (as a method step) that is not required for Groups I or II.

6. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6 and 15-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***WITHDRAWN REJECTIONS***

7. The 35 U.S.C. 103 rejection of claims 1 and 10 made of record in paragraph 11 of the previous Office Action mailed August 9, 2005 has been withdrawn due to Applicant's amendments in claim 1 in Amdt. E, and due to Applicant's cancellation of claim 10 in Amdt. E.

***NEW OBJECTIONS***

***Specification***

8. The amendment filed March 17, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the recitation of claim 14 “wherein the barrel is formed as a unitary structure”: the specification does not disclose that the barrel is formed as a unitary structure, and the Figures do not show the entire barrel (and therefore do not show whether or not the barrel is formed as a unitary structure).

Applicant is required to cancel the new matter in the reply to this Office Action.

***NEW REJECTIONS***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of claim 14 “wherein the barrel is formed as a unitary structure” is not supported in the specification as originally filed since the specification does not disclose that the barrel is formed as a unitary structure, and the Figures do not show the entire barrel (and therefore do not show whether or not the barrel is formed as a unitary structure).

***Claim Rejections - 35 USC § 103***

11. Claims 1, 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al.

In regard to claim 1, Moncada et al. teach a syringe barrel (the combination of syringe barrel, item 84 and adapter, item 80, having a generally continuous surface at the junction of the syringe and the barrel and the adapter, see Fig. 5) comprising a nozzle portion (adapter body, item 20, Fig. 1 and 2 and adapter, item 80, Fig. 5) in which an outer cylinder (flanges, item 116, Fig. 5 and corresponding unlabelled flanges in Fig. 1) and an inner cylinder (cylindrical portion, item 30, Fig. 1 and male Luer lock connector portion, item 106, Fig. 5 ) are formed and a luer lock portion (the space between item 30 and the unlabelled flange in Fig. 1 that corresponds to item 116 of Fig. 5 and the space between items 106 and 116 in Fig. 5) formed in the nozzle portion and between an inner peripheral surface of the outer cylinder and an outer peripheral surface of the inner cylinder (Fig. 1 and 5) (col. 3, lines 62-67, col. 4, lines 2-4, col. 5, line 48-col. 6, line 20). Moncada et al. teach a Luer lock connector having ears (item 122) on the male Luer lock portion of the needle mount (item 94) and threads (item 124) on the female Luer lock portion (item 118) (col. 6, lines 7-16 and Fig. 5). Moncada et al. teach that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23). The portion of the female Luer lock portion (item 118) that has threads (item 124) corresponds the outer cylinder as claimed; Moncada et al. therefore teach that a helically continuous screw thread is formed on the inner peripheral surface of the outer cylinder.

Moncada et al. fail to explicitly teach that the inner peripheral surface of the outer cylinder has a roughened surface.

However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface (a sandblasted surface falls within the scope of this teaching) for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

In regard to claim 11, Moncada et al. fail to explicitly teach that the surface of the screw thread or screw root portion formed between adjacent ridges of the screw thread has a roughened surface.

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However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface (a sandblasted surface falls within the scope of this teaching) for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface (including a sandblasted surface) on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

In regard to claim 12, a sandblasted surface falls within the scope of the teaching of Moncada et al. of other engaging means (col. 6, lines 19-23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the



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desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface (including a sandblasted surface) on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

In regard to claim 14, the barrel of Moncada et al. (the combination of syringe barrel, item 84 and adapter, item 80, having a generally continuous surface at the junction of the syringe and the barrel and the adapter, see Fig. 5) is formed as a unitary structure (Fig. 5).

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Porfano et al.

Moncada et al. teach the barrel as discussed above.

Moncada et al. fail to explicitly teach that the outer cylinder is made of cyclic polyolefin resin. Porfano et al., however, disclose a syringe barrel (item 12) that is made of cyclic polyolefin copolymer resin (col. 6, lines 48). Porfano et al. disclose that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48). Therefore, one of ordinary skill in the art would have recognized to use cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. (including the outer cylinder of the syringe barrel of Moncada et al.) since cyclic polyolefin copolymer resin is a well known material for syringe barrels as taught by Porfano et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. (including the outer cylinder of the syringe barrel of Moncada et al.) since cyclic

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polyolefin copolymer resin is a well known material for syringe barrels as taught by Porfano et al.

*Response to Arguments*

13. Applicant's arguments presented on pages 5-6 of Amdt. E regarding the alleged inapplicability of Moncada et al. to claim 1 as amended have been fully considered but are not persuasive.

Applicant states that "[t]he Office Action concedes that nothing in Moncada – or any other reference of record – teaches roughening a surface in the nozzle portion of a syringe barrel." The Office has not conceded this. The roughening at item 50 taught by Moncada et al. (col. 4, line 52) is a roughened surface in the nozzle portion of a syringe barrel.

Applicant states that "[t]he Office Action argues that it would be obvious to apply roughening to the threaded luer lock (item 118...[...])...", but the previous Office Action mailed August 9, 2005 does not state this (item 118 is not discussed in the context that Applicant alleges item 118 to have been discussed). Item 118 is a female luer lock portion, but it is not the only female luer lock portion (item 92 is another female luer lock portion, and is the counterpart to male luer lock portion 106: these components are the subject of the proposed modification, item 118 is not proposed to be modified).

The teaching of Moncada et al. that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23) is a teaching that the roughened surface of Moncada et al. may be repositioned, and provides motivation to vary the location of the roughened surface of Moncada et al.

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14. In response to Applicant's argument that claim 6 should be rejoined on page 7 of Amdt. E, claim 6 is withdrawn from consideration as being directed to a non-elected invention for the reasons provided above in the *Election/Restrictions* section of this Office Action.

***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is to 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh  
05/17/06

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5/22/06